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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,322	06/21/2005	Hugh Semple Munro	0021.0002	4121

39878 7590 02/17/2009

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EXAMINER	
ZEMEL, IRINA SOPJIA	
ART UNIT	**PAPER NUMBER**
1796	

MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,322	MUNRO ET AL.	
	Examiner	Art Unit	
	Irina S. Zemel	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-52, 54-55, 69-72, 81 -84 and 85* is/are pending in the application.

4a) Of the above claim(s) *47,48 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-46, 49, 51-55, 69-72, 81 -84 and 85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-45, 52, 54-55, 69-85 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Steps of forming an admixture that can be "drained" and step of obtaining a structure having two different portions prior to polymerization that are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). It is noted, that the process as claimed in each of the independent process claims is identical to the process disclosed in the Hahle reference. Yet, according to the Affidavit filed by the applicants, the process of Hahle does not result in the claimed structure having different portions. Therefore, steps that have to be performed to actually obtain the claimed structure must have been omitted from the claimed process.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 40-46, 49, 51-52, 54, 55, 69-72, 81 -84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,136,873 to Hahnle et al., (hereinafter “Hahnle ‘873”).

The rejection stands as per reasons of record.

The newly added limitations are still believed to be inherent in the disclosure of the reference, although not in the preferred or exemplified embodiments.

As evident from the applicants own disclosure, the "draining" is required to achieve the two-layered structure, and the draining is controlled by the viscosity of the reaction mixture. See page 16, l last paragraph and page 22, lines 14-23. The reference also discloses controlling of the reaction mixture viscosity by using or NOT using thickeners. See column 8, lines 49 et seq., where the reference expressly discloses that use of thickeners results in foams that exhibit low shrinkage upon polymerization (see specifically lines 53-55 of column 8). All of the illustrative example use one or the other form of thickeners, that results in more stable foams. The reference expressly discloses that all of the additives, including thickeners and foam stabilizers are used to optimize the structure of the resulting foams. The reference, however, expressly discloses that the polymerization can take in the absence of any thickener. See column 9, lines 62-66. Therefore, production of the foams in the absence of thickeners or foam stabilizers, which inherently will result in less stable foams and foams that shrink more under polymerization condition are within the purview of the reference, and, as disclosed in the reference, addition of such components and control of foam stability of polymerization mixture viscosity is a matter of routine experimentation and optimization. In is further noted, that even in the illustrative examples, foams of equal original volume (like 2 or 3 L), when poured in identical mole result in foams of different thickness, further suggesting that the foams are shrinkable,

and do shrink upon polymerization. As it is well known that lower viscosity foams (in the absence of thickener) will allow some of the bubbles to float to the surface, it is expected that in the absence of any foam stabilizers or thickeners, the resulting product will be the two layer structure corresponding to the claimed structure.

The burden is shifted to the applicants to provide factual evidence to the contrary.

Insofar as the added limitation of claim 85, the reference expressly discloses a possibility of adding addition of a liquid composition containing post-foam crosslinkers (in a form of spray, for example) to the top of foamed and cured hydrogel sheet, with subsequent crosslinking. See, for example, column 13, last full paragraph.

Furthermore, insofar as any process claim is concerned, none of the process claims distinguish the claimed portions as layers, thus reading on any portion of the foam. Since the foams disclosed in the reference clearly disclose highly foamed portion, and also substantially unfoamed polymeric cell walls, which read on the "second portion", the claimed limitations of “portions” is met by virtually any foam in the absence of structurally, or otherwise defined "portions".

The invention as claimed, thus, is fully within the purview of the cited reference, and the choice of specific components from expressly disclosed components would have been an obvious choice of an ordinary artisan with reasonable expectation of success.

Response to Arguments

Applicant's arguments filed 12-19-2008 have been fully considered but they are not persuasive. The applicants argue that the foams disclosed in Hahle are very stable and that they are not expected to result in hydrogels having two different layers, one of which is foamed and another is almost non-foamed. The examiner agrees that the preferred embodiments disclosed by Hahle, most likely, are too stable and viscous to "drain" upon being deposited in a mold and crosslinked. The examiner also agrees with the analysis presented in the declaration. However, all of the analysis and discussion is concentrated on the preferred embodiments disclosed in the reference. However, the disclosure of the reference is not limited to the preferred embodiments only. As discussed above, it is evident from the applicants own disclosure, the “draining” is required to achieve the two-layered structure, and the draining is controlled by the viscosity of the reaction mixture. As further discussed above, the reference also discloses controlling of the reaction mixture viscosity by using or NOT using thickeners. Also as discussed above, lack of any modifiers, stabilizers and thickeners would result in more shrinkable, less stable foams that inherently result, upon polymerization, in the claimed structure.

The applicants further argue that in view of the expressed disclosure of the reference that preferred gas is a gas inert to the free radical polymerization, use of air containing oxygen would not have been obvious. The examiner already addressed this point in the previous office action. Specifically the examiner stated that the “reference

expressly discloses that inert gases are preferred, thus implying that other gases are also possible to employ. Since the claimed gas, air, is predominantly composed of inert (to free radicals) gases (nitrogen, carbon dioxide), its use would have been obvious for an ordinary artisan for at least the economic reasons with reasonable expectation of success and in the absence of showing of unexpected results that can be attributed to the use of air in place of disclosed nitrogen or other gases." In addition, since it is well known in the art (and as argued by the applicants) that oxygen is an inhibitor of free radical reactions, it is expected that use of air will somewhat inhibit the foaming polymerization reaction, but again in view of economic reasons, use of a cheap gas in place of more expensive gas, even though, the rate of production may be sacrificed, is a simple matter of efficiency of the production process.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Irina S. Zemel/
Primary Examiner, Art Unit 1796

Irina S. Zemel
Primary Examiner
Art Unit 1796

ISZ